



May 25, 2021

U.S. Environmental Protection Agency Document
Processing Desk / 6(a)(2) notification
Office of Pesticide Programs
Document Processing Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA. 22202

Dear Sir or Madam:

Subject: FIFRA 6(a)(2) Report

Please find enclosed a FIFRA 6(a)(2) Incident and Effect Information. Valent BioSciences LLC is reporting a case of possible contamination in some of our product, VectoBac 12AS Biological Larvicide.

The active ingredient in VectoBac 12AS Biological Larvicide is *Bacillus thuringiensis* subsp. *isrealensis* strain AM65-52.

Attached is the voluntary reporting form with the available information. If I can be of further assistance, please contact me at (847) 968-4725.

Sincerely,

A handwritten signature in black ink, appearing to read 'Maria', followed by a long, horizontal, wavy line that extends to the right.

Maria Pilar Herrero
Regulatory Manager
(847) 968-4725
Email: Maria.herrero@valentbiosciences.com

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page 1 of 4

Row 1 Administrative Data	Reporter Name Maria Pilar Herrero		Submission date 5-25-2021	Contact person (if different than reporter)	Internal ID		
	Address Valent BioSciences LLC 1910 Innovation Way, Suite 100 Libertyville, IL 60048			Address			
	Phone # 1-847-968-4725 1-847-274-1592 (cell)			Phone #			
	Incident Status: New <input checked="" type="checkbox"/> Update <input type="checkbox"/> If update, include date of original submission. NEW	Location and date of incident. (City, County, State) Massachusetts		Date registrant became aware of incident. 26 April 2021	Was incident part of larger study? Y <input type="checkbox"/> N <input checked="" type="checkbox"/> U <input type="checkbox"/>		
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) 73049-38		EPA Registration # (Product 2)		EPA Registration # (Product 3)		
	A.I. (s) Bacillus thuringiensis subsp, israelensis, strain AM65-52		A.I. (s)		A.I. (s)		
	Product 1 Name VectoBac 12AS Biological Larvicide Aqueous Solution		Product 2 Name		Product 3 Name		
	Exposed to concentrate prior to dilution? Y <input type="checkbox"/> N <input type="checkbox"/> U <input checked="" type="checkbox"/> NA		Exposed to concentrate prior to dilution? Y <input type="checkbox"/> N <input type="checkbox"/> U <input type="checkbox"/> NA		Exposed to concentrate prior to dilution? Y <input type="checkbox"/> N <input type="checkbox"/> U <input type="checkbox"/> NA		
	Formulation Aqueous suspension		Formulation		Formulation		
Row 3 Incident Circumstances	Evidence label directions were not followed? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> U <input type="checkbox"/> Intentional misuse <input type="checkbox"/>	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). Not applicable. The Massachusetts Department of Agriculture Resources (MDAR) took samples of Product 1 in Waltham and Georgetown, Massachusetts and conducted analytical testing of the samples at an unknown location.			Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). Not applicable. MDAR took samples of Product 1 in Waltham and Georgetown, Massachusetts and conducted analytical testing of the samples at an unknown location.		
	Applicator certified PCO? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> U <input type="checkbox"/>						

How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff)	Brief description of incident circumstances. Not applicable. MDAR took samples of Product 1 in Waltham and Georgetown, Massachusetts and conducted analytical testing of the samples at an unknown location.
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Voluntary Industry Reporting Form for 6(a)(2) Incident Information

Voluntary Industry Reporting Form for 6(a)(2) Incident Information

Unauthorized Residue in Food and Feed

Provide all known information. If required data field information is unknown, designate as such in appropriate area. Page3 of4

This is a report of information about the potential contamination of a pesticide product being made under and in accordance with 40 C.F.R. § 159.179(b). MDAR took samples of Product 1 at customers' locations in Waltham and Georgetown, Massachusetts on March 2 and March 15, 2021, respectively, and then conducted analytical testing of the samples on an unknown date and at an unknown location. MDAR analyzed the product samples for any of 25 different per- and polyfluoroalkyl substances (PFAS).

As regards three samples of Product 1 taken by MDAR from 2.5-gallon high density polyethylene (HDPE) bottles at a customer's location in Waltham, Massachusetts on March 2, 2021, MDAR found the following PFAS in two of the three samples at an estimated value based on an unknown limit of quantitation (LoQ), in the quantities indicated:

Perfluorooctanoic acid (PFOA), 19.7 and 23.6 ng/L

As regards the same three samples of Product 1, MDAR also found the following PFAS in all three of the samples. Unknown LoQ

Perfluorononanoic acid (PFNA), 73.7 – 226 ng/L	(estimated values)
Perfluorooctanesulfonic acid (PFOS), 2,760 – 5,040 ng/L	There is an indication of an interfering peak.
Perfluorodecanoic acid (PFDA), 61.8 – 124 ng/L	(estimated values)
Perfluoroundecanoic acid (PFUnA), 169 – 272 ng/L	(estimated values)

As regards one additional sample of Product 1 taken by MDAR from a 30-gallon HDPE drum at a customer's location in Georgetown, Massachusetts on March 15, 2021, MDAR found the following PFAS in the sample in the quantity indicated:

Perfluoroundecanoic acid (PFUnA), 192 ng/L (estimated value)

MDAR provided the foregoing analytical results to Valent BioSciences LLC (VBC) verbally on April 26, 2021 and then again in a spreadsheet delivered by electronic mail on April 30, 2021.

May reporting on 9 lots in the 30 gallon found
 Perfluorooctanesulfonic acid (PFOS), 2,320 – 2,680 ng/L There is an indication of an interfering peak.

VBC understands that MDAR has provided EPA with portions of the same samples of Product 1 that MDAR took on March 2 and March 15, 2021 and then analyzed for PFAS and that are described in this report.

Amount of Pesticide detected
 Possible contaminant
 See the discussion in the immediately preceding section.

Sample type Pesticide product packaged, labeled, and released for shipment.	Sampling times/frequency 9 samples for the 30-gallon HDPE drum. 3 samples for the 2.5-gallon HDPE bottles.
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Method of analysis Unknown	Tolerance Level Not applicable
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Voluntary Industry Reporting Form for 6(a)(2) Incident Information

This box can be used to provide any explanatory or qualifying information surrounding the incident (add additional pages if necessary).

The sampled containers of Product 1 were returned to VBC by the customers and not used.

Internal ID#
